APR - 9 2002

K 013067

SECTION 17: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

17.1 SUBMITTER INFORMATION

a. Company Name:	FRIADENT GmbH.
b. Company Address:	Steinzeugstrasse 50 Mannheim D-68229 Germany
c. Company Phone: Company Facsimile:	(011) 49 06 21 4 86 1549 (011) 49 06 21 4 86 1866
d. Contact Person:	Heike Dietzler Regulatory Affairs Manager
e. Date Summary Prepared:	January 30, 2002

17.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	FRIALOC® Dental Implant System
b. Classification Name:	Endosseous Dental Implants 21 CFR 872.3640

17.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Nobel BioCare	Conical Mk II 3.75mm Fixture	K925760	10/05/93
NobelBiocare	Branemark System Implants	K992937	02/29/00
FRIADENT GmbH	FRIALIT-2 Dental Implant With Deep Profile Surface	K945847	03/15/95

17.4 DEVICE DESCRIPTION

The FRIALOC Dental Implant System consists of transgingival threaded dental implants in 3.5 and 4.0mm diameters with 10 – 18mm lengths. The implants are coated with the FRIOS Deep Profile Surface. The FRIALOC Dental Implant System is comprised of dental implants, surgical and laboratory instruments and prosthetic components. The system is designed for immediate prosthetic loading using bar-retained overdentures in the edentulous mandible. The FRIALOC Dental Implant System can be used for two stage procedures for freestanding posterior maxillary and mandibular bridges.

17.5 SUBSTANTIAL EQUIVALENCE

The FRIALOC® dental implant is substantially equivalent to the current FRIALIT-2® Dental Implant Systems in terms of design, materials, coatings and prosthetic options. The FRIALOC® dental implant is substantially equivalent to the Nobel BioCare Conical Mk II dental implant in terms materials, functionality, mechanical strength and intended use.

17.6 INTENDED USE

FRIALOC Dental Implants are indicated for single stage implant placement, with a minimum healing phase of three months in good quality bone and four months in spongy bone, for free-standing maxillary and mandibular bridges and bar-retained overdenture restorations. The bridge must be supported by a minimum of two FRIALOC transgingival threaded implants. In the edentulous maxilla, a minimum of four FRIALOC transgingival threaded implants are placed in a trapezoidal distribution and rigidly splinted together. In the edentulous mandible, a minimum of four FRIALOC transgingival threaded implants are placed between the mental foramina and rigidly splinted together. In this case, bar prosthetic loading is possible immediately after implant placement.

17.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the FRIALOC® dental implant with the predicate devices is provided within this submission. The FRIALOC® dental implant is identical to the current FRIALIT-2® dental implants in terms of coatings, materials and prosthetic options. The FRIALOC® dental implant is available in a 3.5 and 4.0 mm stepped screw-type with FRIOS® Deep Profile Surface.

The FRIALOC Dental Implant system is equivalent to the Nobel BioCare Branemark Standard Dental Implant System in terms of design, mechanical strength and intended use.

17.8 CLASS III CERTIFICATION AND SUMMARY

This notification contains a Class III certification and summary of adverse safety and effectiveness information pursuant to 513(f) of the Federal Food, Drug, and Cosmetic Act.

17.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2002

Friadent GmbH
Ms. Carol Patterson
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K013067
Trade/Device Name: FRIALOC® Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: January 30, 2002
Received: January 31, 2002

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013067

INDICATION FOR USE

510(k) Number: K013067

Device Name: FRIALOC® Dental Implant System

Indications for Use:

The FRIALOC Dental Implant System is indicated for single-stage implant placement, with a minimum healing phase of three months in good quality bone and four months in spongy bone, for freestanding maxillary and mandibular bridges and bar-retained overdenture restorations. The bridge must be supported by a minimum of two FRIALOC transgingival threaded implants.

In the edentulous maxilla, a minimum of four FRIALOC transgingival threaded implants are placed in a trapezoidal distribution and rigidly splinted together.

In the edentulous mandible, a minimum of four FRIALOC transgingival threaded implants are placed between the mental foramina and rigidly splinted together. In this case, bar-prosthetic loading is possible immediately after implant placement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K013067

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)